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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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1350 Connecticut Avenue NW
Washington, DC 20036

EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,980

Applicant(s)

DIEING ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/21/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application is a 371 (a national stage entry) of PCT/EP00/01070, International Filing Date: 02/10/2000 which claims foreign priority to German 199 07 587.5 under 35 U.S.C. 119(a)-(d). The copy of certified copy of the priority has not been filed with the instant Application. It is noted that PCT/EP00/06997 and German 199 07 587.5 are in German.

Applicant's preliminary amendment in response to the Restriction Requirement, submitted July 10, 2003 is acknowledged wherein Claims 1-31 have been amended. Currently, claims 1-31 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-15 wherein claims 1-20 drawn to a method for improving hold or elasticity of a hairstyle by employing the particular polymers composition, and claims 21-25 the particular polymers composition submitted July 10, 2003 is acknowledged.

The traversal is on the ground(s) that unity of invention exists between "an independent claim for a given product...and an independent claim for a use of the said product." PCT Administrative Instructions, Annex B, Pad 1(e); see also PCT AI, Annex B, Pad 2, Example 1. This is found persuasive. Thus, as indicated above, claims 1-15 as amended now, a use of the said product which is the method herein, will be on the merits herein with the product, claims 21-25, the composition claims.

However, the inventions of claims 26-31 drawn to "a polymer" are not considered to belong to the same general inventive concept as the invention of claims 1-25 since the particular composition of claims 21-25 and a polymer in claims 26-31 are separate and distinct products since a polymer is not a composition. Thus, the invention of claims 1-25 are not considered to belong to the same general inventive concept as the invention of claims 26-31.

According to 37 CFR 1.475 (d), if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See PCT Article 17(3)(a) and § 1.476(c). Thus, claims 1-25 are examined herein as the main invention.

Claims 26-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objection

Claim 15 is objected to under 37 CFR 1.75(c), as being of a multiple dependent claim, i.e., "as claimed in claims 1 to 14". Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 12-14, and 16-25 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular and specific polyether-containing compounds such as those disclosed in claims 2 (b) and 6(b), and the particular and specific copolymerizable monomers in (c) for preparing particular polymers for improving hold or elasticity of a hairstyle disclosed in the specification, does not reasonably provide enablement for any substances or compounds represented by “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” employed in the claimed method herein.

Moreover, note that any “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” broadly encompass those known and unknown compounds as of the instant filing date, as well as those future known compounds yet to be synthesized and/or discovered.

Further, one skilled in the art would clearly recognize that “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” could encompass widely varying and numerous compounds.

Furthermore, the recitations, “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for improving hold or elasticity of a hairstyle by employing the particular polymers composition obtained by the particular polymerization of the particular monomers or polymers in specific amounts.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims read on those known and unknown “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” as of the instant filing date.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does “little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. The CAFC further clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus..” at 1406 (emphases added).

In the instant case, “polyether-containing compounds” and “copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions of the original monomers” recited in the instant claims are purely functional distinction. However, the specification merely provides the particular and specific polyether-containing compounds such as those disclosed in claim 2 (b), and the particular and specific copolymerizable monomers in (c) for preparing particular polymers for the claimed method.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the cosmetic art is unpredictable, requiring each embodiment to be individually assessed for physical and chemical properties, e.g., hold or elasticity of a hairstyle. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physical and chemical properties of any compounds or polymers encompassed in the composition.

As indicated above, the recitations broadly encompass those known and unknown compounds as of the instant filing date, as well as those future known compounds yet to be discovered and/or synthesized. Thus, those unknown or future known compounds must require additional or future research to discover, synthesize,

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establish or verify their usefulness. Therefore, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that the specification merely provides those particular compositions in the examples employed in the claimed method herein (see page 31-37 of the specification). Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the widely varying monomers and polymers encompassed by the claims. See MPEP § 716.02(d).

Since any significant structural variation to monomers and polymers would be reasonably expected to alter its properties, one of ordinary skill would be required to perform undue experimentation to determine which, if any, other polymers compositions would be useful in the claimed method for improving hold or elasticity of a hairstyle.

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent

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protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims employed in the claimed method, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "partial hydrolysis " is a relative term which renders these claims indefinite. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to the recitation " partial hydrolysis " in the claims. Thus the scope of the claims is indefinite as to this recitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Blankenburg et al. (WO 99/04750, equivalent to US 6,403,074, PTO-892).

Blankenburg et al. (see US 6,403,074) discloses that the particular polymers which read on or to the instant polymers such as the formula disclosed at X- $C(O)CR^7=CHR^6$ at col.2 lines 41-66, reads on the vinyl ester of C1-C24-carboxylic acids (a) herein; those polymers prepared from the monomers having formula (I) at col.7 line 15 to col.8 line 5, reads on the recitation (b) in claim 2 and in particular same as the recitation (b) claim 6, are useful in the particular cosmetic compositions and/or formulations with specific amounts of ingredients within the instant claims, in the use for hair care such as hairsprays, setting foams, hair mouse, and hair gel (see 6,403,074 the particular examples at col. 8-14 and claims 1-7, especially claims 6-7).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,579,953.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a pharmaceutical presentation which is interpreted as a composition or formulation, comprising the same ingredients as the instant claims.

Thus, the instant claims 21-25 are seen to be anticipated by the claims 1-6 of U.S. Patent No. 6,579,953.

Claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of U.S. Patent No. 6,403,074.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a haircare composition or formulation, comprising the same ingredients as the instant claims, as discussed in the 102(a) rejection set forth above.

Thus, the instant claims 21-25 are seen to be anticipated by the claims 4-7 of U.S. Patent No. 6,403,074.

Claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,770,293.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a soft capsule shell composition, comprising the same ingredients as the instant claims.


Thus, the instant claims 21-25 are seen to be anticipated by the claims 1-25 of U.S. Patent No. 6,770,293.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 22, 2004